JUN - 5 2000

K000820

510(k) Summary of Safety and Effectiveness

Date Prepared: March 6, 2000

Submitted by: Endosonics Corp.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact Person: Richard Hebert, VP of QA and Regulatory/Clinical Affairs
Phone Number: (800) 228-4728
Fax Number: (916) 638-8062

Device Name: Avanar™ F/X 2.9F Intravascular Ultrasound Imaging Catheter
Common Name: Intravascular Ultrasound Imaging Catheter
Classification Name: Intravascular Diagnostic Catheter
Predicate Device: Visions F/X 3.5F Model 82700 catheter - 510(k) K944004

Device Description:
The Avanar F/X 2.9F Catheter contains a catheter-tip ultrasound device that applies ultrasound energy directly into the interior vessel wall of the patient to obtain an image of the vessel. This device is not currently indicated for use in cerebral vessels. The catheter accommodates a 0.014" guide wire. The catheter utilizes an integral guide wire lumen in which the catheter tracks over the guide wire at the distal tip. The guide wire exits from the guide wire lumen approximately 25 cm proximal to the catheter tip. The catheter is introduced percutaneously or via surgical cutdown into the vascular system. A linear array ultrasonic transducer situated circumferentially near the tip of the catheter produces real time cross-sectional images of the coronary and peripheral vessels.

Intended Use:
The Avanar F/X 2.9F Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The Avanar F/X 2.9F Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

510(k) Summary (cont'd)

Device Technological Characteristics and Comparison to Predicate Device:
The Avanar F/X 2.9F Catheter utilizes the same fundamental scientific technology and intended use as that of the predicate device, Visions F/X 3.5F Model 82700 catheter. The design of the ultrasound imaging transducer, software and hardware are the same. The catheter hub and electrical connector assembly (with the exception of additional length of the microcable) are the same. The difference between the two catheters lies in the catheter shaft design and materials. The Avanar F/X 2.9F Catheter uses a new shaft construction and high performance materials to improve physical dimensions, enhance catheter performance and simplify manufacturing processes.

Performance Data:
Applicable testing was performed (in accordance with FDA Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices, 5/94) to evaluate the changes in the Avanar F/X 2.9F Catheter. The test results of the Avanar F/X 2.9F Catheter were found to be comparable to those of the predicate device, Visions F/X 3.5F Model 82700 catheter. All new materials were tested for biocompatibility according to ISO 10993-1.

Conclusion:
The Avanar F/X 2.9F Intravascular Ultrasound Imaging Catheter utilizes the same fundamental scientific technology and intended use as that of the predicate device, Visions F/X 3.5F Model 82700 catheter. The performance data and a declaration of conformity with design controls support a determination of substantial equivalence of the modified device, Avanar F/X 2.9F Intravascular Ultrasound Imaging Catheter to the predicate device, Visions F/X 3.5F Model 82700 catheter.

K000820
Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2000

Endosonics Corp.
C/O Christina Kichula, Consultant
M2 Worldwide
1401 Rockville Pike, Suite 300
Rockville, MD 20852

Re: K000820
Trade Name: Avanar F/X 2.9F Intravascular Ultrasound Imaging Catheter
Regulatory Class: II
Product Code: DQO
Dated: May 9, 2000
Received: May 9, 2000

Dear Ms. Kichula:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000820

Device Name: Avanar F/X 2.9F Intravascular Ultrasound Catheter

Indications for Use:

The Avanar F/X 2.9F Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The Avanar F/X 2.9F Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Mark N Milbern

for (Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000820

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)